

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Malakowski, et. al.	) Certificate of Mailing
Serial No.: 09/764,609	I hereby certify that this paper is being deposited with the United States Postal Service with
Filed: January 17, 2001	sufficient postage as first class mail in an envelope addressed to: Mail Stop Non Fee  Amendment Commissioner for Patents, P.O. Box
For: Surgery System	1450, Alexandria, VA 22313-1450 on this date:
Group Art Unit: 3739	) March 2, 2004
Examiner: Leubecker	RECEN
Docket No.: 29997/035A	Registration No. Attorney for Applicant(s)  Registration No. APR 16 2004  PECHNOLOGY CENTER R3700
Customer No.: 29471	) CENTER RO-
	13/00

#### Declaration of Dr. Michael Nogler M.D. made under Rule 132

I, Dr. Michael Nogler declare as follows:

- 1. That I am a surgeon specializing in orthopaedic surgery and my Curriculum Vitae outlining my education and specializations is attached as Exhibit A.
- 2. That I am currently a consulting surgeon for the Stryker Corporation, a related entity to the assignee of the present application.
- 3. That I am familiar with the use of surgical navigation systems and instruments in the total knee arthroplasty, total hip arthroplasty and I have used a number of different surgical navigation systems in the past including passive navigation tracking systems and a system that uses wireless hand pieces of the type as claimed in the present application. As noted in my Curriculum Vitae, I have lectured on the use of image guided technology (surgical navigation) for total knee arthroplastics, total hip arthroplastics, spine surgeries.
- 4. That I understand that the present patent application is claiming the use of wireless communication between the surgical navigation system and the individual instruments in combination with other elements of the currently pending claims

- 5. That I understand that the current application has been rejected because the invention as claimed is considered obvious in view of a patent that discloses a wired or tethered instrument communicating with a surgical navigation system.
- That I believe that the use of wireless communication between an active smart instrument and a surgical navigation system has been recognized as a significant advance today and I believe it would not have been considered as obvious on January 27, 2000 for the reasons set forth below:
- a. The use of a wireless system simplifies the setup prior to a typical total joint arthroplasty;
- b. In total joint surgeryy there are a large number of instruments and devices in the surgical field that require power cords, suction tubes and the like.
- c. The use of a wireless hand piece that can be tracked by the surgical navigation system is much less cumbersome and provides a significantly greater range of motion to me in performing these surgical techniques allowing me to perform these tasks properly, in less time, and with lower fatigue. A wired hand piece has a wire that drags, can catch on other instruments and wires, and will actually pull against the direction I need to move the hand piece.
- d. The use of a wireless hand piece minimizes issues relating to maintenance of the surgical field in a sterile state because there is no requirement to pass a portion of the cord to a technician to attach the hand piece to the surgical navigation computer.

Thereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. §1001 and that such willful false statements may jeopardize the validity of the above referenced application or any patent issued thereon.

Michael Nogler, M.D. MA, MSc.

Daw.

# Curriculum Vitae

#### Michael Gerd Maria Nogler

Geb. Datum: 14.09.1964

ao. Univ.- Prof. (Associate Professor for Orthopaedic Surgery)

Medical Doctor

Master of Arts (political science)

Master of Advanced Studies (Hospital management)

Master of Science (Public Health)

# **Ausbildung**

07. July 1988	Received MA degree in political science. Thesis: The foreign policy of the Peoples republic of China and the third world. Univ Prof. Dr. Zdenek Mlynar
WS 1988	- "Teaching and Research Assistant" at the University of New Orleans, Department of Political Science
	- Coworker at the project: Foreign Policy of the Peoples Republic of China, bei <i>Prof. Larry Katzenstein</i>
1989	Grand from the Goverment of Thailandat the Chulalongkorn University in Bangkok: Impact of an eport-oriente economic policy on the development of a domestic market.
Nov. 1995	MD degree
Feb. 2000	research project at the "Maurice E. Müller Institut für Biomechanik", Bern, Switzerlan: Initial stability of the ABG stem. ROBODOC vs. Manual implantation, <i>Prof. Lutz Nolte</i>
Nov. 2001	Promotion to Associate Professor of Orthopaedic surgery
April 2002	MAS degree
April 2002	MSc degree

## **Professional**

# **Medical training**

1996	Start training at the Dpt. of Orthopaedic Surgery, University of Innsbruck. Member of the CAOS Research Group
since 1996	Responsible for Hospital infomation systems at the office of the medical director of the hospital. Member of the data security board.
since 1997	Head of the CAOS Research Group
since 2000	Member of the IT commission of the Medical University of Innsbruck
Nov 2002	Board certification

# **Teaching**

1988	Teaching assistent at the University of New Orleans, College 4. year
1989 - 1992	Dpt. of political science, University of Innsbruck: "Intrioduction to Information Technology"
since 1997	Univ Klinik für Orthopädie: "Bedside Teaching"
since 1999	Univ Klinik für Orthopädie: "CAOS and Robotics"
2001	Robot – assisted hip revision in Osaka and Sapporo, Japan
since 2003	MIS-Hip arthroplasty

#### Areas of research

- Computer assisted Orthopaedic surgery (CAOS) Total Joint Arthroplasty
- Workplace security
- Minimally invasive hip arthroplasty

#### **Prices**

Posterprice "Österreichischen Gesellschaft für Hämatologie und Onkologie" 1996

Spine Society of Europe, Basic Science Award 2001

# Member of professional societies

- Austrian Association of Orthopaedic Surgeon
- CAOS International

Innsbruck, 02.03.04

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ao Univ.- Prof. Mag. Dr. Michael Nogler MAS, MS

Universitätsklinik für Orthopädie

Anichstr. 35

A-6020 Innsbruck

Tel: +43-512-504-80371 FAX: +43-512-504-2701

e-mail: mlchael.nogler@uibk.ac.at

To. Bill Frank

12 pages From Surgen Wagner

Received

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# List of publications

McCracken And Frank

# Original papers

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- Baubin, M.; Schirmer, M.; Nogler, M.; Semenitz, B.; Falk, M.; Kroesen, G.; Hortnagl, H.; and Gilly, H.: Rescuer's work capacity and duration of cardiopulmonary resuscitation. Resuscitation, 33(2): 135-9, 1996
- Baubin, M.; Nogler, M.; Semenitz, B.; Falk, M.; Kroesen, G.; Hortnagi, H.; and Gilly, H.: Active compression-decompression cardiopulmonary resuscitation in standing position over the patient: pros and cons of a new method. Resuscitation, 34(1): 7-10, 1997
- Wimmer, C.; Nogler, M.; and Frischhut, B.: Influence of antibiotics on infection in spinal surgery: a prospective study of 110 patients. J Spinal Disord, 11(6): 498-500, 1998
- Nogler, M.; Wimmer, C.; Mayr, E.; and Ofner, D.: The efficacy of using search engines in procuring information about orthopaedic foot and ankle problems from the World Wide Web. Foot Ankle Int, 20(5): 322-5, 1999
- Bach, C. M.; Nogler, M.; Wimmer, C.; Stoeckel, B.; and Ogon, M.: Fistula between a total hip arthroplasty and the rectum: a case report. Clin Orthop, 388: 143-6, 2001

- 7. Bach, C. M.; Steingruber, I. E.; Peer, S.; Nogler, M.; Wimmer, C.; and Ogon; M.: Radiographic assessment in total knee arthroplasty. Clin Orthop, (385): 144-50, 2001
- 8. Nogler, M.; Krismer, M.; Haid, C.; Ogon, M.; Bach, C.; and Wimmer, C.: Excessive heat generation during cutting of cement in the Robodoc hip-revision procedure. *Acta Orthop Scand*, 72(6): 595-9, 2001
- 9. **Nogler, M.; Krismer, M.; Waldenberger, P.; Rachbauer, F.; and Bach, C.:** Multiple previous surgeries, infection, and preoperative radiation: A cause for arterial rupture in closed reduction? *J Arthropiasty*, 16(8): 1075-1077, 2001
- 10. Nogler, M.; Lass-Flori, C.; Ogon, M.; Mayr, E.; Bach, C.; and Wimmer, C.: Environmental and body contamination through aerosols produced by high-speed cutters in lumbar spine surgery. *Spine*, 26(19): 2156-9, 2001
- 11. Nogler, M.; Lass-Flori, C.; Wimmer, C.; Bach, C.; Kaufmann, C.; and Ogon, M.: Aerosols produced by high-speed cutters in cervical spine surgery: extent of environmental contamination. *Eur Spine J*, 10(4): 274-7, 2001 EUROSPINE Basic Science Award!
- 12. Nogler, M.; Maurer, H.; Wimmer, C.; Gegenhuber, C.; Bach, C.; and Krismer, M.: Knee pain caused by a fiducial marker in the medial femoral condyle: a clinical and anatomic study of 20 cases. *Acta Orthop Scand*, 72(5): 477-80, 2001
- 13. Nogler, M.; Wimmer, C.; Lass-Flori, C.; Mayr, E.; Trobos, S.; and Gegenhuber, C.: Contamination risk of the surgical team through ROBODOC's high-speed cutter. *Clin Orthop*, (387): 225-31, 2001
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- 15. Steingruber, T. E.; Bach, C. M.; Wimmer, C.; Nogler, M.; and Buchberger, W.: Multisegmental pneumatocysts of the lumbar spine mimic osteolytic lesions. *Eur Radiol*, 11(5): 845-8, 2001
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- 17. Bach, C. M.; Nogler, M.; Steingruber, I. E.; Ogon, M.; Wimmer, C.; Gobel, G.; and Krismer, M.: Scoring systems in total knee arthroplasty. *Clin Orthop*, (399): 184-96, 2002

- 18. Bach, C. M.; Steingruber, I. E.; Ogon, M.; Maurer, H.; Nogler, M.; and Wimmer, C.: Intrapelvic complications after total hip arthroplasty failure. *Am J Surg*, 183(1): 75-9, 2002
- 19. Bach, C. M.; Sturmer, R.; Nogler, M.; Wimmer, C.; Biedermann, R.; and Krismer, M.: Total knee arthroplasty infection: significance of delayed aspiration. *J Arthroplasty*, 17(5): 615-8, 2002
- 20. Bach, C. M.; Wachter, R.; Stockl, B.; Gobel, G.; Nogler, M.; and Frischhut, B.: Significance of talar distortion for ankle mobility in idiopathic clubfoot. *Clin Orthop*, (398): 196-202, 2002
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- 28. Nogler, M.; Lass-Flori, C.; Wimmer, C.; Mayr, E.; Bach, C.; and Ogon, M.: Contamination during removal of cement in revision hip

arthroplasty. A cadaver study using ultrasound and high-speed cutters. J Bone Joint Surg Br, 85(3): 436-9, 2003

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- 39. Stoecki, B.; Kessler, O.; Krismer, M.; Mangat, J.; Moctezuma, J.; and Nogler, M.: Variation of entry point selection for the transepicondylar axis and it's quantitative effects. *J Arthroplasty*, 2004 submitted!

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- 3. **Nogler M**, Andreas A, Welss H, Maier H, Tötsch M, Mikuz G, Schmid KW, Öfner D (1996): AgNOR analysis in Ki-67 negative and positive Benign and malignant cells. Fourth International Workshop on Applications of AgNOR in Pathology, Taormina
- 4. **Nogler M** (1997): The problems of cutting through the major trochanter in the ROBODOC ® procedure. Robodoc Usermeeting, Vienna
- 5. Wimmer C, Krismer M, Gluch H, **Nogler M**, Walochnik N (1998): Treatment of idiopathic scoliosis with CD-instrumentation. Lumbar pedicle srews versus laminar hooks. in JBIS Supplement 80-8, Eurospine, Innsbruck
- 6. **Nogler M**, Wimmer C, Mayr E (1998): Die Verfügbarkeit von Informationen über Gelenksendoprothetik im world wide web. in Z. Orthop 136, Deutscher Orthopädenkongreß, Wiesbaden
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- 12. Ogen M, **Nogler M** (1998): Die externe Kommunikation der Univ. Klinik für Orthopädie. Eine Befragung von 400 niedergelassenen Ärzten. Symposium: Der Patient in der Informationsgesellschaft, Innsbruck
- 13. **Nogler M**, Ogon M, Fleisch G, Wimmer C (1998): Kosten Nutzen und rechtliche Aspekte des Einsatzes neuer Kommunikationsmedien zur Aruztbriefübermittlung am Beispiel der Univ. Klinik für Orthopädie Innsbruck. Symposium: Der Patient in der Informationsgesellschaft, Innsbruck
- 14. Bach C, Wimmer C, Nogler M, Frischhut B, Krismer M (1999): Behandlungsstrtegien bei Hüfttotalendoprothesen mit Pfannenlagerdestruktion. Ortho Mitteilungen 2:9. Jahrestagung der Österreichischen Gesellschaft für Orthopädie und Orthopädische Chirurgie, Gmunden
- 15. Bach C, Wimmer C, **Nogler M**, Frischhut B, Krismer M (1999): Infiziertes pseudoaneurysma durch eine intrapelvin dislozierte Pfanne nach Hüfttotalendoprothesenversorgung. Ortho Mitteilungen 2:9. Jahrestagung der Österreichischen Gesellschaft für Orthopädie und Orthopädische Chirurgie, Gmunden
- Ogon M, Hartig F, Nogler M, Bach C, Steingruber I (1999): Bringt der Patellaersatz im Langzeitverlauf Vorteile? Ortho Mitteilungen 2:9. Jahrestagung der Österreichischen Gesellschaft für Orthopädie und Orthopädische Chirurgie, Gmunden
- 17. Wimmer C, Gegenhuber C, Bach C, Nogler M (1999): Die Fusionsrate der Posterolateraien Spondylodese nach Wiltse. Ortho Mitteilungen 2:9. Jahrestagung der Österrelchischen Gesellschaft für Orthopädie und Orthopädische Chirurgie, Gmunden
- 18. **Nogler M**, Wimmer C, Lass-Flörl C, Mayr E, Stöckl B (1999): Detection of the aerosol cloud produced by ROBODOC'S ® high-

- speed bone burr. A contamination risk for the surgical team, in JBJS 81-B Supplement, EFORT Brüssel
- Stöckl B, Wimmer C, Krismer M, Landauer F, Nogler M (1999): Two year migration results of the Duraloc cup. in JBJS 81-B Supplement, EFORT Brüssel
- Stöckl B, Nogler M, Krismer M, Biedermann R, Wimmer C (1999): Lumbar pedicle screws versus laminar hooks in the treatment of idiopathic scollosis with CD-instrumentation. in JBJS 81-B Supplement, EFORT Brüssel
- 21. Bach C, Wimmer C, Freund M, Steingrüber I, **Nogler M** (1999): Two degenerative pneumocysts of the lumbar spine in one patient. A case Report. JBJS 81-B Supplement, EFORT Brüssel
- 22. **Nogier M**, Wimmer C, Mayr E, Landauer F, Stöcki B (1999): Chevron osteotomy with lateral soft tissue release for the treatment of hallux valgus deformity. in JBJS 81-B Supplement, EFORT Brüssel
- 23. **Nogler M**, Wimmer C, Lass-Flörl C, Mayr E, Bach C, Krismer M (1999): Is there a contamination risk for the surgical team through ROBODOC'S high-speed bone cutter? 4Th CAOS Symposium, Davos
- 24. Ogon M, Riedl-Huter C, Nogler M, Krismer M, Spratt KF, Wimmer C (1999): The value of spine radiographs in predicting low back pain under high performance training. 59. Jahrestagung der Schweizerischen Gesellschaft für Orthopädie,
- 25. Bach C, **Nogler M**, Wimmer C, Frischhut M, Krismer M (1999): Treatment of severe total hip arthroplasty loosening. HIP 99-Hip surgery developments and future prospects, Toulouse
- 26. Bach C, Wimmer C, Nogler M, Steingruber I (1999): Hematuria secundary to transpelvic dislocation of total hip arthroplasty - a case report. HIP 99-Hip surgery developments and future prospects, Toulouse
- 27. Wimmer C, Stöcki B, **Nogler M**, Bach CM (2000): Conservative treatment of tuberculous spondylitis. Euro Spine J 9:360-1
- 28. **Nogler M**, Krismer M, Waldenberger P, Rachbauer F, Bach C, Ogon M (2000): Rupture of the arteria profunda femoris during cloes reduction in a dislocated hip-arthroplasty. in JBJS B Supplement, 4th Domestic Meeting, European Hip Society, Bristol, UK
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- 31. Bach C, Trobos S, **Nogler M**, Wimmer C, Stöckl B (2000): Total hip arthroplasyt infection following pneumonia. in JBJS B Supplement, 4th Domestic Meeting, European Hip Society, Bristol, UK
- 32. Krismer M, **Nogler M**, Kaufmann C, Ogon M (2000): Revision of femoral cement removal by obot vs. Manual procedure. in JBJS B Supplement, 4th Domestic Meeting, European Hip Society, Bristol, UK
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- procedure. 5th International Symposium on CAOS, Davos
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